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10/695,038

10/28/2003

Michael James Justin

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BIOMERIEUX, INC.  
PATENT DEPARTMENT  
100 RODOLPHE STREET  
DURHAM, NC 27712

EXAMINER

NAGPAUL, JYOTI

ART UNIT

PAPER NUMBER

1743

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/695,038

Applicant(s)

JUSTIN ET AL.

Examiner

Jyoti Nagpaul

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "said carrier comprises ***an upper surface and a lower surface*** and ***first and second side regions***, and wherein said positioning features comprise ***voids*** formed in a rib depending from said ***lower surface***, said rib placed between ***said first and second side regions***" as recited in Claim 3 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites, "wherein said positioning features comprises voids formed in a rib ***depending*** from said lower surface". What does applicant mean by a rib ***depending*** from said lower surface?

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-3 and 8** are rejected under 35 U.S.C. 102(b) as being anticipated by Maes (EP 0 896224).

Maes discloses an analytical instrument for conducting biological sample testing. The instrument comprises a carrier/carousel segment (670) for movement of test sample devices/test sample cards. The carrier comprises N optical interrupt positioning features/tabs (691) that is formed in the carrier (670). Additionally, each of the positioning features/tabs (691) is placed in registry with one of the receiving

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structures/slots (614). Furthermore, the detection of one of the positioning features/tabs (691) is by a fixed optical interrupt sensor (693) in the sample testing instrument (100) and further detects a position of a test sample device/card placed in the receiving structure/slot (614) corresponding the positioning feature/tab (691). The carrier (670) is moved through the instrument (100) in a direction having a longitudinal axis. The test sample devices/cards are oriented in the carrier (670) in a direction orthogonal to the longitudinal axis. The positioning features/tabs (691) are arranged on the carrier (670) in a direction parallel to the direction of movement of the carrier (604) in the instrument (100). The carrier (670) comprises an upper surface and a lower surface and first and second side regions, and wherein the positioning features comprise voids formed in a rib depending from the lower surface. The rib placed between the first and second side regions. The fixed optical interrupt sensor (693) is positioned in the instrument along the path of movement of the carrier (670) wherein the rib passes over the optical interrupt sensor (693). (See Figure below) Maes further teaches the test sample devices comprises multi-well test sample cards.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. **Claims 4-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maes (EP 0 896224) in view of Clark.

Refer above for the teachings of Maes.

Maes fails to teach the carrier/carousel segment further comprises a first portion having a handle and opposite second portion having a flat panel. The flat panel having a bar code associated with the carrier/carousel segment. Maes further fails to teach the carrier further comprises N test tube receiving structures placed in registry with the N test device receiving structures/slots.

Clark teaches an analytical instrument for chemical, immunochemical and biological testing of samples. Clark teaches a carrier/carousel segment (626) comprises a first portion having a handle (601) and opposite second portion having a flat panel (624) for receiving a bar code associated with the carrier/carousel segment. Clark further teaches N test tube receiving structures placed in registry with in registry with the N test device receiving structures/slots. (See Figures 36-39)

Maes does teach manual removal and insertion of a section /carousel segment (670). Thus, it would have been obvious to a person of ordinary skill in the art to modify the device of Maes to provide a first portion having a handle in order to further assist the operator for easy removal and insertion of the carousel segment into and out of the instrument as disclosed in Clark.

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Bar codes are conventionally known in the art. Thus, it would have been obvious to a person of ordinary skill in the art to modify the device of Maes to provide an opposite second portion having a flat panel for receiving a bar code associated with the carrier/carousel segment in order to assist the operator in easily identifying the samples in the carrier as disclosed in Clark.

Test tubes are conventionally known in the art for holding samples. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the device of Maes to provide N test tube receiving structures placed in registry with in registry with the N test device receiving structures/slots in order to further diversify the use of the carrier.

6. **Claims 6-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maes in view of Stevens (US 4582990).

Refer above for the teachings of Maes.

Maes fails to teach the carrier further comprises alphanumerical indicia for the receiving structures and the alphanumerical indicia numerals provided on the carrier 1 to N in registry with the receiving structures.

Stevens teaches a test tube tray/carrier comprising alphanumerical indicia (205) provided on the carrier 1 to N with the receiving structures. (See Figure 7)

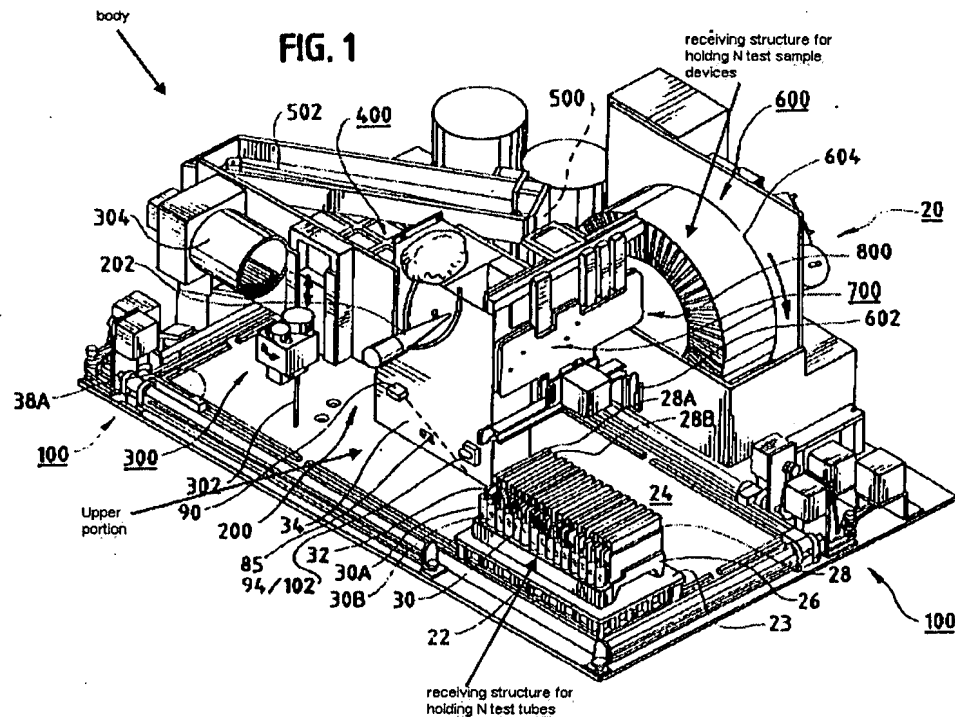
It would have been obvious to a person of ordinary skill in the art to modify the device of Maes to provide alphanumerical indicia numerals provided on the carrier 1 to N in registry with the receiving structures in order to assist the operator in proper location of the test samples in the slots.



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7. **Claims 9 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maes in view of Clark.

Maes teaches an analytical instrument for conducting biological sample testing. The instrument (100) comprises a body having an upper portion and a lower portion and second side portions. The instrument further comprises receiving structures in the upper portion for holding up to N test sample devices and up to N test tubes containing test samples. (See Figure below) Maes further teaches N optical interrupt positioning features/tabs (691). Each of the positioning features (691) placed in registry with one of the receiving structures/ carrier segment (614). Furthermore, the detection of one of the positioning features/tabs (691) is by a fixed optical interrupt sensor (693) in the sample testing instrument (100) and further detects a position of a test sample device/card placed in the receiving structure/carrier segment (614) corresponding the positioning feature/tab (691). Maes further teaches the sample devices comprise multiwell test sample cards.



Maes fails to teach the carrier/carousel segment further comprises a first portion having a handle and opposite second portion having a flat panel. The flat panel having a bar code associated with the carrier/carousel segment.

Clark teaches an analytical instrument for chemical, immunochemical and biological testing of samples. Clark teaches a carrier/carousel segment (626) comprises a first portion having a handle (601) and opposite second portion having a flat panel (624) for receiving a bar code associated with the carrier/carousel segment. Clark further teaches N test tube receiving structures placed in registry with in registry with the N test device receiving structures/slots. (See Figures 36-39)

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Maes does teach manual removal and insertion of a section /carousel segment (670). Thus, it would have been obvious to a person of ordinary skill in the art to modify the device of Maes to provide a first portion having a handle in order to further assist the operator for easy removal and insertion of the carousel segment into and out of the instrument as disclosed in Clark.

Bar codes are conventionally known in the art. Thus, it would have been obvious to a person of ordinary skill in the art to modify the device of Maes to provide an opposite second portion having a flat panel for receiving a bar code associated with the carrier/carousel segment in order to assist the operator in easily identifying the samples in the carrier as disclosed in Clark.

8. **Claims 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Maes in view of Clark as applied to claim 9 above, and further in view of Stevens (US 4582990).

Refer above for the teachings of Maes and Clark.

Maes and Clark fail to teach the carrier further comprises alphanumerical indicia for the receiving structures and the alphanumerical indicia numerals provided on the carrier 1 to N in registry with the receiving structures.

Stevens teaches a test tube tray/carrier comprising alphanumerical indicia (205) provided on the carrier 1 to N with the receiving structures. (See Figure 7)

It would have been obvious to a person of ordinary skill in the art to modify the device of Maes and Clark to provide alphanumerical indicia numerals provided on the

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carrier 1 to N in registry with the receiving structures in order to assist the operator in proper location of the test samples in the slots.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JN

BRIAN R. GORDON  
PRIMARY EXAMINER

